AMENDED IN SENATE JUNE 3, 2003

AMENDED IN SENATE MAY 1, 2003

AMENDED IN SENATE APRIL 21, 2003

SENATE BILL No. 322

Introduced by Senator Ortiz

February 19, 2003

An act to add *and repeal* Sections 125118, 125119, 125120, ~~125121, and 125122~~ *and 125121* ~~to~~ *of* the Health and Safety Code, relating to medical research.

LEGISLATIVE COUNSEL'S DIGEST

SB 322, as amended, Ortiz. Stem cell research ~~proposals~~.

Existing law states the policy of the state that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given, and that research involving the derivation and use of these cells shall be reviewed by an approved institutional review board.

This bill would require the ~~Director of the~~ State Department of Health Services to ~~establish a Human Stem Cell Research Review Council, to be comprised of specified members. This bill would require the council to~~ develop guidelines for research involving the derivation or use of human embryonic stem cells in the state. ~~The bill would provide that it is unprofessional conduct for any licensed health care provider to conduct research concerning human embryonic stem cells in a manner that does not comply with these guidelines. The bill would authorize the council to take specified actions if the council determines~~

~~that a researcher is conducting research in a manner that is in conflict with the guidelines.~~

This ~~bill would also impose specified reporting requirements on principal investigators conducting research projects concerning the derivation or use of human embryonic stem cells. The~~ bill would require all *human embryonic stem cell* research projects ~~concerning this topic~~ to be reviewed and approved by an institutional review board *(IRB)* that is established in accordance with federal regulations*, as specified*.

~~This bill would also require the council to report annually to the director and the Legislature concerning its activities.~~

This bill would require an IRB to conduct continuing review of human stem cell research projects, as specified, and would authorize an IRB to require modifications to the plan or design of a continuing research project before permitting the research to continue. This bill would require IRBs to report to the department, as specified, and would require the department to report to the Legislature on human embryonic stem cell research activity. This bill would make these provisions inoperative on June 30, 2006, and would repeal them as of January 1, 2007.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature finds and declares all of the following:

(1) Isolation of human embryonic stem cells represents a major step forward in human biology and has generated much interest among scientists and the public, particularly among patients and their advocates regarding the benefits of human embryonic stem cells and stem cell research.

(2) Because human embryonic stem cells can give rise to many different types of cells, such as muscle cells, nerve cells, heart cells, and others, they are enormously important to science and hold great promise for advances in health care.

(3) Research using human embryonic stem cells may help scientists generate cells and tissue that could be used for transplantation and may someday be used as replacement cells and tissue to treat many diseases and conditions, including Parkinson's disease, spinal injury, stroke, burns, heart disease, diabetes, and arthritis.

(4) Research involving human embryonic stem cells may also improve understanding of the complex events that occur during normal human development and what causes diseases and conditions including birth ~~defects~~ *defects, pediatric brain injury,* and cancer, and may improve the way new drugs are developed and tested for safety and efficacy.

(5) In view of the scientific and medical benefits that may result from research using human embryonic stem cells, it is essential that this research be supported and encouraged. However, in view of the ethical, legal, and social issues relevant to human embryonic stem cell research, it is essential that this research be ~~subjected to oversight more stringent than that associated with the traditional National Institutes of Health scientific peer review process.~~ *subject to oversight that complements and goes beyond the oversight of human subject research provided by the Office for Human Research Protections within the United States Department of Health and Human Services.*

(6) The National Institutes of Health currently has no comprehensive guidelines concerning the ethical, legal, and social issues involved with the derivation and use of human embryonic stem cells in medical research.

(b) Therefore, it is the intent of the Legislature ~~to establish a state entity to~~ *that the State Department of Health Services* develop guidelines for human embryonic stem cell research in California ~~and to review research projects involving the derivation or use of human embryonic stem cells to ensure that these projects are conducted in an appropriate manner and comply with~~ *in order to ensure that this research is guided by* ethical and legal standards.

SEC. 2. Section 125118 is added to the Health and Safety Code, to read:

~~125118. (a) The director shall establish a Human Stem Cell Research Review Council.~~

~~(b) The council shall consist of 13 members, comprised as follows:~~

~~(1) Seven scientists with experience in biomedical research in the fields of cell differentiation, nuclear reprogramming, tissue formation and regeneration, stem cell biology, developmental biology, regenerative medicine, or related fields, who are not currently conducting, and have no plans to conduct, research involving human embryonic stem cells.~~

~~(2) Two medical ethicists.~~

~~(3) Two persons with backgrounds in legal issues involved with human embryonic stem cell research, in vitro fertilization, or family law as it applies to donation of embryos and oocytes.~~

~~(4) Two persons who are members or leaders of religious organizations.~~

~~SEC. 3. Section 125119 is added to the Health and Safety Code, to read:~~

~~125119. (a) The council~~

125118. (a) The department shall develop guidelines for research involving the derivation or use of human embryonic stem cells in ~~California and for review of research projects involving the derivation or use of human embryonic stem cells in California.~~ *California.*

(b) In developing the guidelines specified in subdivision (a), the ~~council~~ *department* may consider other applicable guidelines developed or in use in the United States and in other countries, including, but not limited to, the Guidelines for Research Using Human Pluripotent Stem Cells developed by the National Institutes of Health and published in August 2000, and corrected in November 2000.

(c) This section shall become inoperative on June 30, 2006, and, as of January 1, 2007, is repealed, unless a later enacted statute that is enacted before January 1, 2007, deletes or extends the dates on which it becomes inoperative and is repealed.

~~SEC. 4. Section 125120~~

SEC. 3. Section 125119 is added to the Health and Safety Code, to read:

~~125120.~~

125119. (a) (1) All research projects involving the derivation or use of human embryonic stem cells shall be reviewed and approved by an institutional review board that is established in accordance with federal regulations, *including Part 46 (commencing with Section 46.101) of Subchapter A of Subtitle A of Title 45 of the Code of Federal Regulations*, prior to being undertaken. Any such institutional review ~~board shall ensure that any project that it reviews meets and complies with~~ *board shall, in its review of human embryonic stem cell research projects, consider and apply* the guidelines developed by the ~~council~~ *department* pursuant to ~~Section 125119.~~

~~SEC. 5. Section 125121 is added to the Health and Safety Code, to read:~~

~~125121. (a) The principal investigator in any research project involving the derivation or use of human embryonic stem cells that has been reviewed and approved by an institutional review board that is established in accordance with federal regulations shall submit, or cause to be submitted, to the council established pursuant to Section 125118, on a timetable to be established by the council, progress reports on the research that are sufficient to enable the council to determine that the research continues to comply with the guidelines established by the council.~~

~~(b) The conduct of research involving the derivation or use of human embryonic stem cells in a manner that does not comply with the guidelines established pursuant to Section 125119 by any licensed health care provider shall constitute unprofessional conduct.~~

~~(c) If the council determines that a researcher is conducting research in a manner in conflict with the guidelines established pursuant to Section 125119, it may take any of the following actions:~~

~~(1) Request a modification in the research plan or design.~~

~~(2) Request that the research be discontinued.~~

~~(3) Request that funding for the research be discontinued.~~

~~(4) Refer any investigator or principal to an appropriate licensing board.~~

~~(5) Refer the conduct to any law enforcement body, if appropriate.~~

~~SEC. 6. Section 125122 is added to the Health and Safety Code, to read:~~

~~125122. The council shall report annually to the director and the Legislature on its actions, including the number of research projects that it has reviewed and the status and disposition of those projects.~~ *Section 125118. An institutional review board may require modifications to the plan or design of a proposed human embryonic stem cell research project as a condition of approving the research project.*

(2) For purposes of this article, "IRB" means an institutional review board described in paragraph (1).

(b) Not less than once per year, an IRB shall conduct continuing review of human embryonic stem cell research projects reviewed

and approved under this section in order to ensure that the research continues to meet the standards for IRB approval. Pursuant to its review in accordance with this subdivision, an IRB may revoke its prior approval of research under this section and require modifications to the plan or design of a continuing research project before permitting the research to continue.

(c) This section shall become inoperative on June 30, 2006, and, as of January 1, 2007, is repealed, unless a later enacted statute that is enacted before January 1, 2007, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 4. Section 125120 is added to the Health and Safety Code, to read:

125120. (a) Each IRB that has reviewed human embryonic stem cell research pursuant to Section 125119 shall report to the department, annually, on the number of human embryonic stem cell research projects that the IRB has reviewed, and the status and disposition of each of those projects.

(b) Each IRB shall also report to the department regarding unanticipated problems, unforeseen issues, or serious continuing investigator noncompliance with the requirements or determinations of the IRB with respect to the review of human embryonic stem cell research projects, and the actions taken by the IRB to respond to these situations.

(c) This section shall become inoperative on June 30, 2006, and, as of January 1, 2007, is repealed, unless a later enacted statute that is enacted before January 1, 2007, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 5. Section 125121 is added to the Health and Safety Code, to read:

125121. (a) The department shall at least annually review reports from IRBs pursuant to Section 125120, and may revise the guidelines developed pursuant to Section 125118, as it deems necessary.

(b) The department shall report annually to the Legislature on human embryonic stem cell research activity. These annual reports shall be compiled from the reports from IRBs pursuant to Section 125120.

(c) This section shall become inoperative on June 30, 2006, and, as of January 1, 2007, is repealed, unless a later enacted

statute that is enacted before January 1, 2007, deletes or extends the dates on which it becomes inoperative and is repealed.

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